Cancer Clinical Trials in Montana

Clinical trials are research studies with human participants to evaluate new ways to prevent, diagnose, or treat diseases including cancer. Clinical trials are the final step in the long research process that begins at the laboratory bench, proceeds to animal testing and, only if the research is promising, finally proceeds to human trials. A clinical trial focuses on a particular type of cancer and a particular aspect of treatment. There are four phases of human clinical trials:

- Phase I, involving a small number of participants, to determine the most effective way to administer a new treatment;
- Phase II, to assess the safety and efficacy of a new treatment;
- Phase III, to compare the safety and efficacy of a new treatment to the current standard of care; and
- Phase IV, after a treatment is approved for general use, to monitor ongoing safety in large numbers of people routinely receiving the treatment.

For any new treatment under investigation, research may stop at the bench, with animal testing, or in an early phase of human trials, if the treatment does not appear to be as safe and effective as the current standard of care. Some new treatments *are* safer and more effective and will eventually become the new standard of care, but this can only happen with the proof provided by clinical trials.

All proposed clinical trials must undergo a rigorous, independent ethics review by an Institutional Review Board (IRB), a committee that has been formally designated to review and monitor all biomedical research involving human subjects. The dual roles of the IRB are to ensure that only ethical and scientifically valid research is conducted, and to protect the rights and welfare of human participants in research.

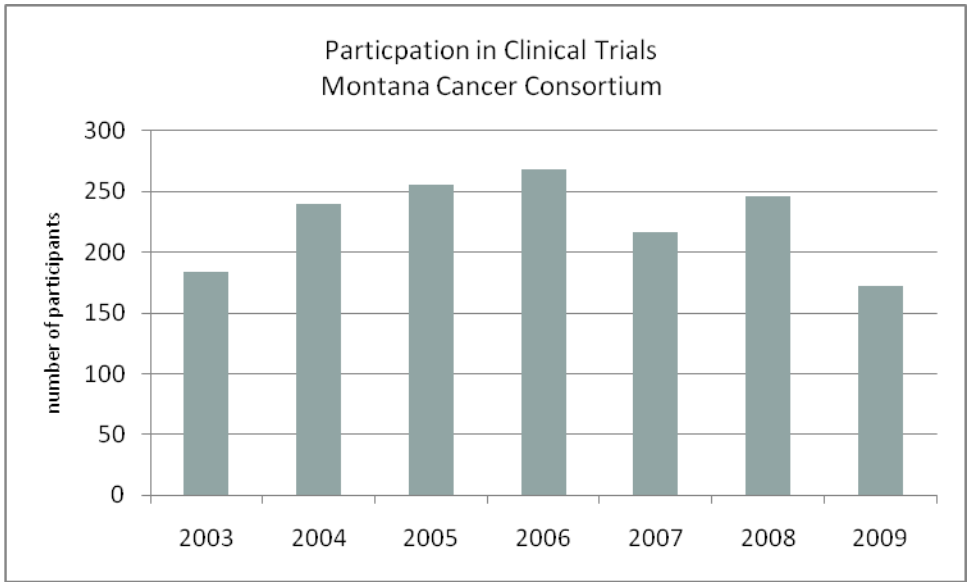
Participants in clinical trials receive either the best current standard of care or a new treatment that has a good possibility of being better than the current standard. Participants can receive cutting-edge treatment that is not yet available to the general public. All clinical trial participants are closely monitored by the research team. There are, however, some risks involved in participation. In spite of careful early evaluation, a new treatment may not be as effective as the current standard of care or it may have more side effects; this is what the clinical trial is designed to evaluate. Participants may be required to visit their doctor or treatment center more often than patients not involved in a clinical trial. Insurance companies sometimes classify clinical trials as "experimental" treatments and decline to cover participants.

Clinical trials are randomized, meaning participants are assigned to a treatment arm at random. Some randomized trials are blinded, meaning neither participants nor research staff know

whether patients are receiving the standard treatment or the new treatment until the end of the clinical trial; other randomized trials are not blinded. Cancer clinical trials almost never use placebos (non-treatment disguised as treatment). All participants in cancer clinical trials receive treatment, either the best that is currently available or something that might be better.

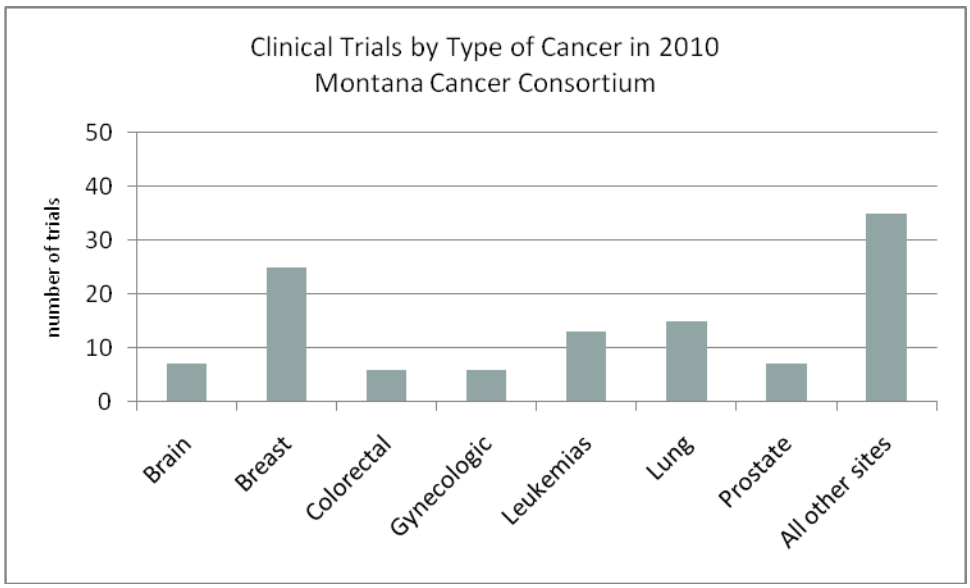
Clinical trials may be sponsored by drug companies, foundations, or individual medical centers, but the majority of large cancer clinical trials are sponsored by federal agencies such as the National Cancer Institute (NCI) or the Veterans' Administration. The Community Clinical Oncology Program (CCOP) of the NCI provides a way for people all across the country, regardless of the size or location of their community, to participate in clinical trials of cancer prevention, screening, treatment, and post-treatment quality of life. The CCOP supports local or regional groups of physicians and institutions to allow their patients access to clinical trials close to home.

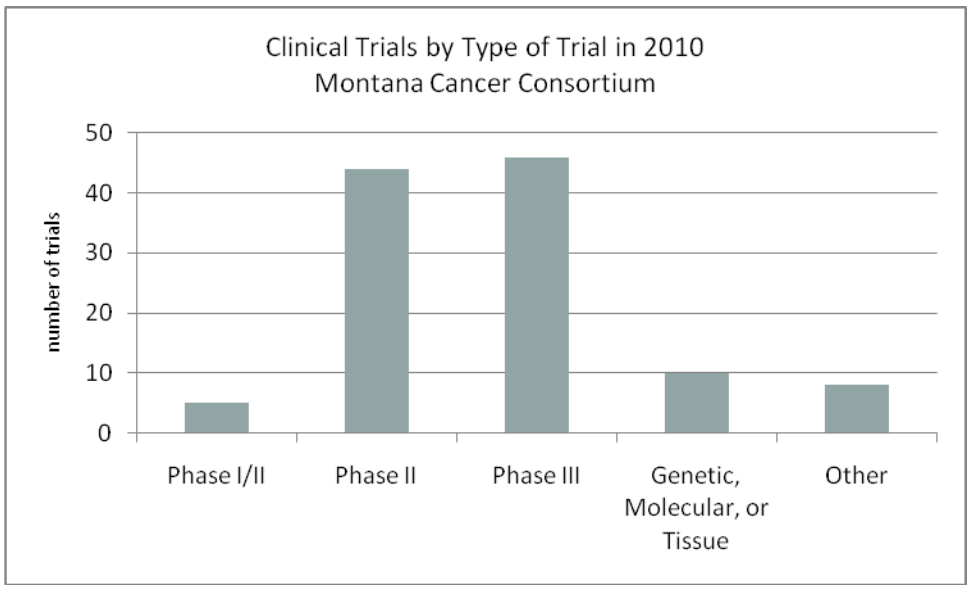
The Montana Cancer Consortium is an independent, not-for-profit institution that has received support from the CCOP since 1996. It is based at Saint Vincent Healthcare in Billings, but it has 20 participating institutions and 46 participating providers throughout Montana and northern Wyoming. Since 1996, more than 4,000 residents of Montana and Wyoming have participated in cancer clinical trials through the Montana Cancer Consortium, which has more than 100 cancer prevention or treatment protocols open at any given time.



The clinical trials currently open at the Montana Cancer Consortium focus on a wide range of cancer types, from the most common (breast and prostate) to less common kinds (brain, leukemia). All phases and types of clinical trials are represented, including state-of-the-art genetic and molecular studies and quality of life studies for cancer survivors.

One hundred twelve women in Montana and Wyoming were among nearly 20,000 women nationwide who participated in the landmark Study of Tamoxifen and Raloxifene (STAR) prevention clinical trial. Tamoxifen has been used since the 1970s as an adjuvant treatment





following surgery for breast cancer. Tamoxifen also showed promise in the prevention of a first tumor in women at incresed risk for breast cancer, but proved to have rare but serious side effects including increased risk of blood clots, strokes, and heart attacks. Raloxifene is currently used to treat osteoporosis in postmenopausal women. The STAR trial demonstrated that both drugs reduce the risk of developing a first breast tumor in postmenopausal women, and that raloxifene has fewer side effects than tamoxifen.

Forty nine men in Montana and Wyoming were among over 35,000 men nationwide who participated in the selenium and Vitamin E Cancer Prevention Trial (SELECT), designed to determine if taking selenium and/or Vitamin E could prevent prostate and other cancers. Participants in this study set a new record for recruitment to clinical trials. This largest-ever postate cancer prevetion trial began enrollemnt in 2001 and finished accrual in less than three years. The

results showed that selenium and vitamin E, taken singly or together for an average of five years, did not reduce the risk of developing prostate cancer. Although the trial outcome might be viewed as negative, in that the treatment regimen did not reduce the risk of cancer, the results are nonetheless valuable in documenting that this was not effective, which will prevent unnecessary use of these supplements and will stimulate further research in prostate cancer prevetion.

Only 3% of US adults with cancer participate in clinical trials, although many more are potentially eligible. Low participation hinders the development of new and effective cancer treatments. Some patients may be fearful of being "experimented on," but lack of awareness is the main reason patients do not participate. A 2001 Harris poll found that 85% of cancer patients were unaware that clinical trials were an option, and of those patients, 75% said they would have been willing to enroll in a trial if they had known it was possible.[1]

MONTANA CANCER CONSORTIUM

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Please visit the Montana Department of Public Health and Human Services Cancer Control Program's website at www.cancer.mt.gov

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[1] http://www.harrisinteractive.com/news/allnewsbydate.asp?NewsID=222